

REMARKS

Claims 2, 5, 7, 9, 14, 76-79 and 81-87 were previously pending in this application. Claims 84-87 have been withdrawn as a result of the species election requirement. Claims 2, 5, 9, 14 and 81 have been amended. As a result claims 2, 5, 7, 9, 14, 76-79 and 81-83 are pending for examination with claims 2 and 9 being independent claims. No new matter has been added.

Rejections Under 35 U.S.C. §112, First Paragraph

The Examiner rejected claims 5, 14, 78 and 83 under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. Specifically, the Examiner has rejected the claims because, according to the Examiner, there is no disclosure in the specification of use of an endosomal targeting peptide of 2-11 amino acids in length.

Applicants have amended claims 5 and 9 to include the term “further” to distinguish the endosomal targeting signal as an additional peptide added to create a fusion protein. Support for this can be found within the specification on page 14, lines 7-23. Applicants believe this clarifies that the endosomal targeting signal is additional to the amino acids that can be added as claimed in claims 2 and 9. Thus this amendment obviates this rejection.

Accordingly, withdrawal of this rejection is respectfully requested.

Rejections Under 35 U.S.C. §102

The Examiner rejected claims 2, 9, and 81 under 35 U.S.C. §102(b) as being anticipated by Fikes et al. (WO 95/04542).

According to the Examiner, Fikes et al. teach a peptide that contains all of the amino acids of SEQ ID NO:7 except the first and last amino acids and that Fikes et al. teach that the amino acid residue Glu can be added at the N-terminus of said peptide.

Applicants have amended claims 2, 9 and 81 to remove the term “deletion” from these claims. The amended claims are not anticipated by Fikes et al. because Fikes does not teach the peptide as claimed.

Accordingly, withdrawal of this rejection is respectfully requested.

Rejections Under 35 U.S.C. §103

The Examiner rejected claims 2, 7, 9, 79 and 81 under 35 U.S.C. §103(a) as being unpatentable over Fikes et al. (WO 95/04542) in view of Gelder et al. (US Patent 6,043,347).

The Examiner has rejected the claims on the basis that claims 2, 9, 81 encompass a peptide that has one amino acid deleted from SEQ ID NO:7 and Fikes et al. teach that the amino acid Glu can be added at the N-terminus of said peptide, yielding the peptide of claim 2. The Examiner further stated that Gelder et al. teach modified peptides containing D-amino acids and it would have been *prima facie* obvious to one of ordinary skill to have created the claimed invention.

Applicants have amended claims 2, 9 and 81 to remove the term “deletion” from these claims. Fikes et al. does not teach the peptide as claimed. If one of skill were motivated by the teachings of Gelder and were to add D-amino acids to the peptide taught by Fikes et al., this would not result in the peptide as claimed.

Accordingly, withdrawal of this rejection is respectfully requested.

The Examiner has further rejected claims 2, 9, 76, 77, 81 and 82 under 35 U.S.C. §103(a) as being unpatentable over Fikes et al. (WO 95/04542). The Examiner has stated that Fikes et al. teach a MAGE-1 peptide that contains all of the amino acids of SEQ ID NO:7 except the first and last amino acids, and that peptides can be optionally flanked by additional MAGE-1 amino acids, and that peptides are less than 15 amino and are about 11 residues, which would encompass a 12mer peptide. According to the Examiner one of ordinary skill in the art would have been motivated to make the aforementioned peptide because Fikes et al. teach that the peptides of their invention are less than about 15 residues in length and usually contain about 11 residues which would encompass a 12mer peptide.

Applicants claim an isolated HLA DRB1*15-binding peptide consisting of the amino acid sequence SEQ ID NO:7 or a functional variant with one amino acid addition or substitution and 0-10 amino acids added to either or both ends of this peptide. Peptide SEQ ID NO:7 is a 12mer peptide to which at least one amino acid may be added creating a 13mer peptide. Applicants further teach that 0-10 amino acids can be added to either or both ends of the peptide.

It is the Applicants assertion that the Examiner has used hindsight reasoning to expand on the teachings of Fikes et al. The peptides taught by Fikes et al. are less than 15 residues, usually consist of between 8 and 11 and are preferably 9 or 10 residues (see page 5, lines 31-38). Fikes et al. also teach a peptide of 10 amino acids (SEQ ID NO:15, sequence list, page 41) which is missing two amino acids of SEQ ID NO:7 and Fikes et al. do not teach how many amino acids should be added to either side of that specific peptide. This general teaching of Fikes et al. is not sufficient to render obvious Applicants' claimed invention. Fikes et al. does not provide one of skill in the art with the requisite specific motivation to modify its peptides, specifically the MAGE-1 peptide similar to Applicants' claimed peptide in a manner that would result in the claimed invention.

Furthermore, Fikes et al. teaches peptides that induce a MHC class I response and one of ordinary skill in the art preparing a MHC class I peptide would not approach making a MHC class II peptide in the same manner. The preferred peptides of Fikes are 9 or 10 amino acids (page 5, lines 35-38) and it is well known in the art that to induce a MHC class I response shorter peptides are preferred (see page 8, lines 12-22, specifically Schumacher et al., (1991), *Nature*, 350:703-706, which states "class I molecules preferentially bound short peptides (nine amino acids)"). In this regard, Applicants note that "it is impermissible within the framework of 35 U.S.C. §103 to pick and choose from any one reference only so much of it as will support a given position to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one skilled in the art." In re Wesslau, 353 F.2d 238, 241, 147 USPQ 391, 393 (CCPA 1965); see also In re Mercer, 515 F.2d 1161, 1165-66, 185 USPQ 774, 778 (CCPA 1975); In re Geiger, 815 F.2d 686, 2 USPQ2d 1276 (Fed. Cir. 1987).

Accordingly, withdrawal of this rejection is respectfully requested.

The Examiner has further rejected claims 7 and 79, under 35 U.S.C. §103(a) as being unpatentable over Fikes et al. (WO 95/04542) as applied to claims 2, 9, 76, 77, 81 and 82, and further in view of Gelder et al. (US patent 6,043,347). The Examiner has rejected these claims because, according to the Examiner, it would have been *prima facie* obvious to one of ordinary skill in the art to have created the claimed invention because Fikes et al. teach the claimed

peptide except for D-amino acid modification, while Gelder et al. teach modified peptides containing D-amino acids and that such peptides exhibit increased stability.

Applicants have amended claims 2, 9 and 81 to remove the term "deletion" from these claims. As noted above, Fikes et al. do not teach the peptide of these claims and one of skill in the art would not be motivated to make the claimed peptides based on the Fikes et al. teaching. Therefore, even if one of skill were motivated to add D-amino acids to the peptide taught by Fikes et al., this would not provide the peptide as claimed.

Accordingly, withdrawal of this rejection is respectfully requested.

CONCLUSION

In view of the foregoing amendments and remarks, this application should now be in condition for allowance. A notice to this effect is respectfully requested. If the Examiner believes, after this amendment, that the application is not in condition for allowance, the Examiner is requested to call the Applicant's attorney at the telephone number listed below.

If this response is not considered timely filed and if a request for an extension of time is otherwise absent, Applicant hereby requests any necessary extension of time. If there is a fee occasioned by this response, including an extension fee, that is not covered by an enclosed check, please charge any deficiency to Deposit Account No. 23/2825.

Respectfully submitted,
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